REMARKS

The status of the claims is as follows:

Original:	None
Currently amended:	1, 6, 9-11 and 19
Previously presented:	12
Canceled:	2-5, 7, 8, 13 and 15-18
Withdrawn:	14
New:	None

With entry of this amendment, claims 1, 6, 9-12, I4 and 19 are pending, wherein claim 14 has been withdrawn. Reconsideration is requested.

Claims 2-5, 7, 8 and 13 are canceled herein. Claims 15-18 were canceled in a previous amendment.

Claim 1 has been amended to incorporate features recited in claims 2-5, 7 and 8.

Claim 6 has been re-written to depend from claim 1 instead of claim 5 which has been canceled.

Claim 9 has been amended to depend from and conform to claim 1 as amended.

Claim 10 has been conformed to claim 9 from which it depends.

Claim 11 has been made dependent upon claim 1.

Claim 19 has been amended to remove recitation directed to preventing.

None of the amendments introduces new matter.

This amendment is being made without prejudice. Applicants reserve the right to pursue any or all of the subject matter recited in the canceled claims and any or all subject matter removed from the pending claims in one or more continuing applications.

Information Disclosure Statement

An information disclosure statement (IDS) accompanies this amendment. The IDS includes: (i) granted US patents or published US patent applications corresponding to several of the published international applications cited in the IDS filed February 11, 2008 and the IDS filed September 8, 2006; (ii) a granted US patent corresponding to a published US application cited in the IDS filed September 8, 2006; (iii) US 2008/0009490 A1; and (iv) US 7211572 (Miyazaki et al.), the application published as US 2007/0161639 A1 (Jones et al.), and papers in the interference declared between Miyazaki et al. and Jones et al.

Election/Restriction

The restriction requirement has been made final. Reconsideration is requested. The Examiner considers Applicants' traversal to be non-persuasive because of Markush practice and refers to MPEP § 1850, section III-B. The reference to Markush practice is not understood. Section III-B is concerned with whether a claim that includes a group of chemical alternatives possesses unity of invention. This was not the issue addressed in the traversal. Applicants traversed the restriction between Group I (claims directed to compounds, a composition containing the compound, and a combination containing the compound) and Group II (claims directed to methods of using the compounds of Group I). Groups I and II represent different categories of claims, and the appropriate reference for unity of invention analysis is MPEP § 1850, section III-A which states:

> The method of determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
>
> (A) In addition to an independent claim for a given product, ... , an independent claim for a use of said product; ... (MPEP § 1850, III-A, paragraph bridging pages 1800-100 and 1800-101)

Group I (claims 1, 6, 9-12 and 19) concerns a product and Group II (claim 14) concerns a use of the product. Group II is a category of invention different from Group I. As is clear from the quoted portion of MPEP § 1850 above, the combination of the claims in Groups I and II is permitted under unity of invention practice.

Although it is believed to have no direct relevance to the traversal, it is noted that the compounds embraced by claim 1 as amended herein meet the Markush criteria described in MPEP § 1850 (section III-B, page 1800-102) in that all alternatives have a common activity (i.e., HIV integrase inhibition) and all alternatives share a significant structural element (i.e., all of the compounds have a 2,3,4,4a,5,6-hexahydro-2,6-naphthyridine-1,7-dione core).

It is accordingly requested that the restriction requirement between Groups I and II be withdrawn and that claim 14 be rejoined.

Allowable Subject Matter

The allowance of claim 11 is acknowledged.

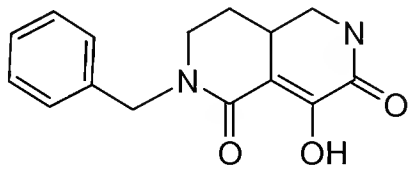
Claim Objection

Claim 10 has been objected to as being dependent upon a rejected base claim. The invitation to rewrite claim 10 in independent form is declined, because it is believed the base claim and intervening claim as amended herein are in condition for allowance.

Rejections under 35 U.S.C. § 112

Claims 1-9, 12 and 19 have been rejected under 35 U.S.C. § 112, first paragraph, as not being in compliance with the written description and enablement requirements. Claims 2-5, 7 and 8 have been canceled rendering the rejections moot as applied thereto. The rejections are traversed with respect to claims 1, 6, 9, 12 and 19 as amended herein.

Claim 1 as amended herein is directed to compounds having a structural core of formula A:



(A)

This core is a significant structural element of all the compounds embraced by the claims, wherein the differences in the compounds lie in the type and number of substituents around the core. The exemplified compounds (Examples 1-18) have structural core A, are within the scope of claim 1, and are representative of the compounds embraced by claim 1. The specification discloses that HIV is the etiological agent responsible for AIDS (page 1, lines 16-19), that integration of the proviral DNA into the host cell genome is a required step in HIV replication (page 1, lines 20-23), and that HIV integrase, the enzyme mediating the integration of the proviral DNA, is one of the enzymes that has been shown to be essential for the replication of HIV (page 1, lines 29-32). The specification also describes in detail the various embodiments recited in claim 1 and its sub-claims, and discloses that the compounds are useful in the inhibition of HIV integrase, the treatment of infection by HIV, the treatment of AIDS and the delay in the onset of AIDS (page 2, lines 26-29; the paragraph bridging pages 21-22).

The specification provides comprehensive guidance and directions on how to prepare the claimed compounds via Schemes 1-8 on pages 25-33 and via Examples 1-15, 17 and 18. The person of ordinary skill in the art would understand from this description that Applicants possessed the knowledge and skill to prepare the claimed compounds and that the person of ordinary skill would be able to prepare the claimed compounds without undue experimentation. The compounds embraced by claim 1 differ by the type and/or number of substituents attached to structural core A (e.g., the choice and number and choice of substituents on the benzyl ring), and thus the preparative schemes may need some modification from compound to compound, but such modification would be within the knowledge and capability of both Applicants and, in light of the teachings of the specification, the ordinarily skilled.

The specification further describes how to test the claimed compounds for integrase inhibition (Example 20) and HIV replication inhibition (Example 21), and discloses that compounds representative of the claimed 2,6-naphthyridine-1,7-diones exhibit inhibition activity in these tests. In particular, the specification discloses that the compounds in Examples 1 to 18 exhibited inhibition activity in the tests (page 56, lines 29-31 and page 57, lines 6-9). The skilled artisan would expect compounds embraced by the amended claims but not specifically disclosed in the

application to have the same biological activity as the exemplified compounds in view of the significant structural feature (structural core A) shared by all of the compounds. The skilled artisan would expect the level of activity to vary with the choice and number of substituents around the core, but would expect some level of activity for such compounds.

The specification also discloses means for administering the claimed compounds (page 23, lines 14-25), provides guidance on the preparation of pharmaceutical compositions for administration of the compounds including a cite to the 18th edition of Remington's Pharmaceutical Sciences (page 23, line 25 to page 24, line 2), and provides guidance on suitable dosage ranges for oral administration of the compounds (page 24, lines 3-16).

This disclosure demonstrates (i) that Applicants had knowledge and possession of the claimed compounds, their preparation, and their utility and (ii) that the person of ordinary skill in the art would be able to practice the claimed invention without undue experimentation. More particularly, using the description provided in the specification, optionally in combination with know-how available in the art, the person of ordinary skill can without undue experimentation prepare and administer a compound of the invention in a suitable carrier and in the appropriate dosage form and dosage amount to a subject in order to inhibit HIV integrase, treat HIV infection, treat AIDS, or delay the onset of AIDS.

In view of the foregoing remarks, it is clear that the instantly claimed invention complies with both the written description and enablement requirements. Withdrawal of the section 112 rejections is accordingly requested.

The application is believed to be in condition for allowance and passage to issue is requested. The Examiner is invited to telephone the undersigned should any minor matters need to be resolved before a Notice of Allowance can be mailed.

Respectfully submitted,

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